

International Conference on Harmonization (ICH)
M2 EWG Meeting - Summary
Washington DC, 04 October to 07 October 1999

Participants:

EU: Esteban Gonzalez Juarros, Karel de Neef, Stan van Belkum
EFPIA: Gabriele Disselhoff, Andrew Marr, Mervyn Mitchard
PhRMA: Kris Arora, Rick Bowen, Bob Hizer
FDA: Greg Brolund (Rapporteur), Melissa Chapman, Robin Jones
JPMA: Hitoshi Asano, Harv Martens, Yuichi Nagoshi, Keiji Sawamukai, Tetsuro Shimokariya
MHW: Kazuhiro Kemmotsu, Daisuke Koide, Emiko Kondo, Yoko Nakamura, Akira Nakata, Mihoko Okada, Kenichi Tamiya, Hiroshi Yamada
Observer: Bob Kapitany

The tasks accomplished and the decisions agreed are the following:

1. "Electronic Transmission of Individual Case Safety Reports Message Specification"
The experience with the pilot performed in Japan results in changes of the DCL, which only reflect the regional implementation. These changes will be made available in an attachment and associated files and immediately published on the WEB site. These changes do not affect the sign-off of the SC. If changes to the DTD are required at some future time, they will go through the ICH maintenance procedure.
2. Specification for the Electronic CTD (eCTD)
 - ☞ the EWG have agreed to develop two 'proofs of concept' (prototypes) to help develop an eCTD specification and have nominated responsible teams
 - ☞ the scope of the 'proofs of concept' has been defined and agreed in the Project Definition working document
 - ☞ the EWG have common understanding that 'proofs of concept' are not the deliverables of the group and will not be implemented in the regions; instead, the expected deliverable of M2 is a specification document that will go through the ICH step process
 - ☞ the 'proofs of concept' will make use of draft documents from the CTD EWGs (where available), will be used to answer conceptual and technical questions and evaluated using the functional requirements collected by the M2 EWG
 - ☞ the initial development will be done between October 1999 and February 2000, additional development, testing and validation between March 2000 and July 2000
 - ☞ depending upon the progress of the CTD EWGs, Step 2 eCTD specification document is possible by ICH5 and Step 4 six months after CTD EWG Step 4 document
 - ☞ DVD-RAM is under consideration as an additional physical media standard
 - ☞ the EWG have presented status and results to the SC
3. Varia
 - ☞ the EWG heard a presentation of CTD S by the rapporteur of CTD S
 - ☞ the three EWG Regulatory Authorities reported on electronic submission status, progress and plans and communication between regulatory authorities and industry

The next M2 meeting will take place in Tokyo, from February 28 - March 2, 2000, as proposed for the ICH Steering Committee meeting.